Purpose To compare the efficacy and safety of evolocumab in the clinical practice with the CT.

Material and methods Retrospective observational study (May 2017 to September 2018) of all evolocumab prescriptions. Demographic, clinical, analytical and treatment variables were collected at baseline and after the first follow-up visit. Efficacy was measured, by the percentage of LDL-C reduction at week 12, using laboratory analysis and medical records. Safety was obtained from medical and pharmaceutical records.

Results Thirty patients (63% male) with a mean age of 62.2 (52–78) were considered for treatment. One of them was not treated because he did not comply with the authorisation criteria (LDL >100 mg/dl). Diagnosis was ASCVD (15/29), statins intolerance (10/29) and FH (4/29). Evolocumab was prescribed in combination with statins in 13 patients, in five with another hypolipemiant and in 11 in monotherapy. The percentage change in LDL-C from baseline in the combination with statins group, was a reduction of 67% ((+7.2%) to (–79.1%)) at week 12 (7–20). In the monotherapy group, it was of 68% ((+24.5%) to (–92.2%)) at week 9 (7–12). Treatment adherence was >96% in all patients. Regarding safety, 20% of patients had an adverse event: itching (2/29), fatigue (1/29), myalgia (1/29), abdominal pain (1/29), diarrhoea (1/29) and glucose alterations (1/29).

Conclusion In clinical practice, the reduction in LDL-C in the monotherapy group was slightly higher than in CT. The adding of statins did not affect the efficacy in our patients, they were similar in both groups. Safety was comparable to CT. It would be interesting to evaluate if these reductions are maintained in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-030

DO WE KNOW WHICH ANTIBIOTICS SHOULD BE AVOIDED IN OUR PATIENTS? ANTIBIOTIC ALLERGY SURVEY AMONG HOSPITALISED PATIENTS

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10.1136/ejhp-2019-eahpconf.464

Background It is known from allergy databases that antibacterials belong to the common sensitising drugs. However, antibacterials are frequently administered in the hospital setting both for prophylactic and for therapeutic purposes. Considering drug allergy is an important drug safety issue, but inadequate allergy labelling can negatively affect drug choice.

Purpose To assess the prevalence and characteristics of antibiotic allergy and to differentiate cases where the allergic nature of drug reaction can be excluded/or has weak grounding.

Material and methods A structured interview guide was used for the face-to-face anonymous interviews with hospitalised adult inpatients.

Results During the 19 study days, among the 1522 hospitalised patients 114 mentioned allergy to systemic antibiotics (7.5%). Most of the patients were allergic to one active agent, (100 patients), while 14 patients were polysensitised (allergic to two or more antibacterials). In the majority of cases (81 cases) penicillin products caused the drug reaction, and second, sulfonamides (18 cases) were mentioned. In 24 cases, the patient did not have any information on signs/symptoms of the drug reaction and in 14 cases drug allergy can be

excluded (e.g. diarrhoea as the only reaction). Most often drug reactions occurred in the hospital setting (30 cases), if not, in 12 cases hospital admission was necessary due to severity. Antibacterials most often resulted in cutaneous reactions (71 cases). Skin reaction/pruritus was the only sign in 48 cases and in 15 cases this reaction happened in childhood. Severe cutaneous drug reaction – EEM and SJ syndrome occurred in seven cases. Unintended drug re-exposure occurred in eight cases, resulting in reactions similar to the earlier ones (in two cases with severe life-threatening anaphylaxis). Only 12 patients (10.5%) had an allergy ‘passport’.

Conclusion Antibiotic allergy was prevalent among the interviewed inpatients. In some of these reactions allergic nature can be excluded by the anamnesis, while other cases had weak evidence due to the complete lack of the anamnesis/childhood occurrence of skin reactions. Only very few patients had an allergy passport. Hospital pharmacists can exclude untrue allergic reactions during the reconciliation process and can help in the proper documentation of drug allergy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We sincerely thank all the participating patients.

No conflict of interest.

5PSQ-031

A TWO-YEAR RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS WITH FLUOROQUINOLONE AND QUINOLONE ANTIBIOTICS

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10.1136/ejhp-2019-eahpconf.464

Background On 9 February 2017, the Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review¹ of disabling and potentially long-lasting side effects reported with systemic and inhaled quinolone and fluoroquinolone antibiotics at the request of the German medicines authority, following reports of long-lasting side effects in the national safety database and the published literature.

Purpose To review the adverse drug reactions (ADRs) of systemic and inhaled fluoroquinolone and quinolone antibiotics that involved peripheral and central nervous system, tendons, muscles and joints reported from our Pharmacovigilance Department (PVD).

Material and methods Retrospective analysis of ADRs reported in our PVD involving ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin, rifloxacin, cinoxacin, nalidixic acid and pipemidic given systemically (by mouth or injection). The period considered was September 2016 to September 2018.

Results Twenty-two ADRs were reported in our PVD involving fluoroquinolone and quinolone antibiotics in the period considered and that affected peripheral or central nervous system, tendons, muscles and joints. The mean patient age was 67.3 years (range: 17–92 years). 63.7% of the ADRs reported were serious, of which 22.7% caused hospitalisation and 4.5% caused persistent/severe disability. 81.8% of the ADRs were reported by a healthcare professional (physician, pharmacist or other) and 18.2% by patients or a non-healthcare professional.

Fluoroquinolone and quinolone antibiotics reported in these ADRs were mainly used for urinary tract infections (40.9%) and respiratory tract infections (31.8%).

Conclusion On 5 October 2018, the European Medicines Agency PRAC recommended restricting the use of fluoroquinolone and quinolone antibiotics² (used by mouth, injection or inhalation), that will become applicable only after the decision of the Committee for Medicinal Products for Human Use. In the meantime, this work could help in make the healthcare professionals aware of a range of possible side effects (apart from achilles tendon disorders) attributable to fluoroquinolone and quinolone antibiotics, and that could be life-changing and wide ranging.

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No conflict of interest.

5PSQ-032 ADMINISTRATION PROTOCOL FOR PENICILLIN G IN A PATIENT WITH A SEVERE REACTION TO BETALACTAMS AND ABDOMINAL ACTINOMYCOSIS

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10.1136/ejhp-pharm-2019-eahpconf.465

Background Penicillin G 20 MIU/day for 4–6 weeks followed by oral amoxicillin for 6–12 months is the first option of treatment for abdominal actinomycosis where other therapies have less effectiveness.

Purpose To describe a desensitisation protocol for Penicillin G in a patient with abdominal actinomycosis that had experienced a severe anaphylactic reaction (tachycardia, redness, bronchospasm and refractory hypotension) to ceftriaxone that required a perfusion of noradrenaline, in addition to adrenaline, corticosteroids and salbutamol for recovering.

Material and methods Penicillin G vials were reconstituted with water for injection as indicated on its label and they were diluted with 0.9% sodium chloride to make four mother solutions (0.1 mg/ml, 1 mg/ml, 10 mg/ml and 100 mg/ml of δ -lactamic). Doses were prepared in syringes. Initial dose was 16 IU, with subsequent syringes elaborated doubling the dose until a cumulative dose of 5 MIU. A total of 19 syringes were prepared in a horizontal laminar flow cabinet in the pharmacy service: dilution 0.1 mg/ml (160 IU/ml): 16 IU/0.1 ml, 32 IU/0.2 ml, 64 IU/0.4 ml and 128 IU/0.8 ml. Dilution 1 mg/ml (1,600 IU/ml): 240 IU/0.15 ml, 480 IU/0.3 ml, 960 IU/0.6 ml and 1,600 IU/1 ml. Dilution 10 mg/ml (16,000 IU/ml): 3,200 IU/0.2 ml, 6,400 IU/0.4 ml and 12,800 IU/0.8 ml. Dilution 100 mg/ml (160,000 IU/ml): 24,000 IU/0.15 ml, 48,000 IU/0.3 ml, 96,000 IU/0.6 ml, 16,000 IU/1 ml, 320,000 IU/2 ml, 640,000 IU/4 ml, 1,280,000 IU/8 ml and 2,400,000 IU/15 ml.

Results Due to the high risk of the patient, despite negative allergological tests, a desensitisation protocol was administrated by allergists in the intensive care unit with monitoring and

cardiopulmonary resuscitation equipment. The time interval between each syringe was 10 min in direct bolus, the last three doses were administered during 10–15 min due to the higher doses and infusion pain. The schedule was achieved without any reaction. After this, a whole dose of 5 MUI/6 hours was administered during 2 months without any adverse reaction.

Conclusion This desensitisation protocol can be useful for penicillin-allergic patients without alternative treatment options.

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No conflict of interest.

5PSQ-033 EFFECTIVENESS OF COMPUTERISED DECISION SUPPORT SYSTEM-BASED INTERVENTION IN ANTIMICROBIAL USE: THE HIGEA PROJECT

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10.1136/ejhp-pharm-2019-eahpconf.466

Background Clinical decision support systems (CDSS) can play an important role in facilitating antimicrobial stewardship programmes (ASP). However, the effects of CDSS in improving antimicrobial therapy have been insufficiently studied.

Purpose To evaluate the impact of an automated/integrated real-time CDSS called HIGEA for antimicrobial stewardship-related interventions.

Material and methods This was a prospective descriptive study performed in a 1300-bed tertiary teaching hospital in Madrid.

A CDSS was developed integrating microbiology data, laboratory data and the computerised prescription order system. The integration was performed using a standard language (HL7). The system generates alerts based on predefined clinical rules (CR) to select patients in whom antimicrobial therapy can be improved. Alerts are reviewed daily by an infectious disease pharmacist, who makes recommendations of the necessary changes on the treatment to the physician.

Eight custom-built CR that promote stop/de-escalation of therapy were evaluated in the initial ASP review during 1 April 2017–31 August 2017. Data collection included total number of actionable alerts, recommendations provided and acceptance rates. For each CR, the positive predictive value (PPV) was calculated as the ratio of modifications in treatment to alerts reviewed. The severity of medication errors prevented and antimicrobial consumption were also analysed.

Results In total, 701 alerts were reviewed during the study period (6.4 alerts per day). Overall, 419 (60%) alerts were actionable. The acceptance rate was 77% (321/419) and the PPV 0.46. The CR that induced the highest number of treatment changes was ‘treatment with penicillins/cephalosporins/quinolones>7 days’ (PPV=0.58), followed by ‘switch to oral therapy with quinolones/linezolid/azole’ (PPV=0.31), ‘Streptococcus/Enterococcus+carbapenem’ (PPV=0.70) and ‘candidin +fluconazole sensitive *Candida*’ (PPV=0.82).